

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-7 and 10 are pending in this application. Claims 1-7 are amended and claims 8-9 have been cancelled. Claims 1 and 3 are the independent claims. Claim 10 has been withdrawn from consideration.

Applicants note with appreciation the Examiner's acknowledgement that certified copies of all priority documents have been received by the U.S.P.T.O. Action, summary at 12.

Abstract Objections

Applicants have made the suggested corrections to the abstract as indicated by the Examiner. Therefore, withdrawal of the objection to the abstract is respectfully requested.

Claim Objections

Claims 1-9 have been objected to for informalities. The claims have been amended as suggested by the Examiner. Applicants respectfully request that the objections to claims 1-9 be withdrawn.

Rejections under 35 U.S.C. § 112

First Paragraph

Claim 8 stands rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for treating lupus, multiple sclerosis,

rheumatoid arthritis, rheumatism, osteoporosis, asthma, tale and mane eczema, does not reasonably provide enablement for treating any disorders in mammals. Claim 8 has been cancelled, and therefore, the rejection of claim 8 is now moot. The Applicants, therefore, respectfully request that the rejection to Claim 8 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Second Paragraph

Claims 1-9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that, for instance, Claim 1 recites "a first composition including leaves of *Melissa officinalis*, or parts thereof", and it is uncertain what Applicant means by that "parts thereof"; asked does it mean any parts of the *Melissa officinalis* plant can be used in the first composition, such as roots, flowers, barks, seeds?; stated that, if that is the situation, then the recitation of "roots of *Glycyrrhiza glabra*", "roots of *Uncaria tomentosa*" seems unnecessary, as any parts of the plant will do; and that, for the same reason, it applies to 2nd to 6th compositions.

Applicants have amended the claims to provide further clarification and overcome the Examiner's concerns. The Applicants, therefore, respectfully request that the rejection to Claims 1-9 under 35 U.S.C. § 112, second paragraph, be withdrawn.

Example Embodiments of the Present Application

Independent claims 1 and 3 recite a kit for use in the treatment of lupus, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, and asthma in humans or tail and mane eczema in horses. Example non-limiting embodiments of this feature are discussed, for example, in paragraph [0031] of the instant specification.

As is illustrated in paragraph [0031] of the present application, the kit is used to treat lupus and/or tail or mane eczema in mammals, for example, horses. Example 1 illustrates that treatment of a patient with the kit according to example embodiments, followed by exposure to sunlight, did not lead to inflammation whereas such an effect did occur before treatment. The kit lifts the system-reticulo-endothelial blockade and improves biofeedback, thereby leading to an overall improvement in the horse's physical condition.

Rejections under 35 U.S.C. § 103

Flynn, Widy-Tyszkiewicz, Singh, McClung and Sandoval

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Flynn (The herbal management of stress, Australian journal of medical herbalism, 1996: 8 (1): 15-18), Widy-Tyszkiewicz et al (A randomized double blind study of sedative effects of phytotherapeutic containing valerian, hops, balm and motherwort versus placebo, Herba polonica, (1997) Vol. 43, No. 2, pp. 154-159), Singh et al (Therapeutic potential of Kava in the treatment of anxiety disorders, CNS drugs 2002: 16 (11): 731-743), McClung (US 6579543) and Sandoval (Cat's claw (Uncaria tomentosa)

protects against oxidative stress and indomethacin-induced intestinal inflammation, *Gastroenterology*, 1997; 112 (4 suppl.): A1081). Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that Flynn teaches herbs that offer an extremely successful way to manage both physiological and psychological response to stress; that *Avena sativa* is great to use in cases of ongoing stress to feed and restore the nervous system; that Flynn also teaches *Avena* feeds the nervous system in an active sense as a nutrient, and is therefore useful as a long term measure in any stress condition; that *Glycyrrhiza glabra* has wide application to stress, both in adrenal support and for stress-induced problems; that *Eleutherococcus senticosus* studies have shown it to increase both mental and physical stamina during periods of stress by up to 70%, and it also counters the debility and stress of chronic disease and surgery; that Flynn does not teach using *Avena sativa*, *Glycyrrhiza glabra*, and *Eleutherococcus senticosus* in one kit, neither does Flynn teach the incorporation of *Melissa officinalis*, *Piper methysticum*, *Ballota nigra*, or *Uncaria tomentosa* into the kit; neither does Flynn teach the pharmaceutical form of tablet or capsule; that Widy-Tyszkiewicz et al teach a commercially available anti-stress tablets (thus at least one composition is in the form of a capsule or tablet) containing 50 mg of balm leaves (*Melissa officinalis*) etc (page 154, 2nd paragraph from the bottom); that it is deemed that a tablet contains a pharmaceutically acceptable carrier such as a binding agent; that Singh et al teach kava (*Piper methysticum*) has been shown to be effective in mild to moderate cases of anxiety. Its biological activity, due to a mixture of compounds called

kavalactone, are reported to include antistress properties etc (see Abstract) (thus a fourth composition in claim 3); that McClung teaches an antidepressant/anti-anxiety/anti-stress compound is selected from the group consisting of black horehound etc (the same as *Ballota nigra*), Sandoval teaches *Uncaria tomentosa* protects cells against oxidative stress (see Abstract) (thus sixth composition); that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted); that in the instant case, all of the above-listed ingredients were known for anti-stress activity. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for anti-stress activity; that it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for anti-stress activity pharmaceutical art; that accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him; that therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Flynn, Widy-Tyszkiewicz et al, Singh et al, McClung, and Sandoval since all of them teach compositions for anti-stress activity individually in the art;

that, since all the compositions yielded beneficial results for anti-stress activity, one of ordinary skill in the art would have been motivated to make the modifications to combine the references together; and that thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary. The Examiner bases this opinion on documents wherein each individual plant of the composition according to the kits of claims 1 and 3 is associated with anti-stress activity. Consequently, the Examiner alleges that it would be obvious for the skilled person to make this composition and use it for its alleged anti-stress activity conferred by the individual components for the treatment of stress-induced or related disorders. Applicants respectfully disagree.

As set forth in more detail below, Applicants respectfully submit that Flynn, Widy-Tyszkiewicz, Singh, McClung and Sandoval do not teach or suggest that the individual plant extracts, let alone the composition as claimed, can be used for the treatment of lupus in humans or tail and/or mane eczema in horses as is recited in claims 1 and 3.

First, Flynn describes the application of herbs in a general context of managing both physiological and psychological responses due to stress. Flynn describes three components: *Avena sativa*, *Glycyrrhiza glabra* and *Eleutherococcus senticosus*. As cited by the Examiner, *Avena sativa* is “great to use in case of ongoing stress to feed and restore the nervous system” and as “restorative for nervous debility, fatigue [...] depression [...] neurasthenia, neuralgia and herpes” (page 17, middle part left column). *Eleutherococcus senticosus* is disclosed in connection with “increasing mental and physical

stamina” and for countering “debility and stress of chronic disease and surgery” by reducing “adrenal hypertrophy and depletion” (pages 16 and 17). As pointed out by the Examiner, *Glycyrrhiza glabra* has been described to have wide applicability in relation to stress, in adrenal support and for stress-induced problems. However, Applicants submit that there is no disclosure in Flynn that the plants can be used for the treatment of lupus in humans or tail and/or mane eczema in mammals.

Regarding anti-stress activity, Widy-Tyszkiewicz describes an anti-stress tablet comprising *Valeriana officinalis*, *Leonurus officinalis*, *Melissa officinalis* and *Strobili lupulus*. Widy-Tyszkiewicz describes *Melissa officinalis* as useful for treatment of neurotonic disorders and insomnia (page 154, middle section). Widy-Tyszkiewicz does not clarify if the anti-stress activities are caused by *Melissa officinalis*, any of the other plants or the specific combination thereof.

As the Examiner points out correctly, Singh discloses the use of *Piper methysticum* as being effective in treating mild to moderate cases of anxiety. Further, Applicants submit that Singh teaches away from the use of the plant to treat lupus in humans or tail and/or mane eczema in mammals as recited in claims 1 and 3, because Singh discloses that “adverse effects attributed to kava (or *Piper methysticum*) use were mild or negligible, except for the occurrence of skin lesions” (page 731, bottom paragraph), which can lead to dermopathy. One skilled in the art, being aware that lupus and eczema are disorders which are clearly manifested through the skin, would, therefore, not be motivated to use the plant disclosed in Singh for the treatment of a skin disorder.

Despite the anti-stress effects of black horehound, McClung does not teach or suggest that *Ballota nigra* can be used to treat lupus in humans or tail and/or mane eczema in horses as recited in claims 1 and 3.

In addition, Sandoval, in particular, does not teach or suggest a plant for use in the treatment of lupus in humans or tail and/or mane eczema in horses as recited in claims 1 and 3. Sandoval describes a study “to investigate whether [...] *Uncaria tomentosa* is a protective agent against oxidant-induced stress in macrophages”. An extract of this plant provided protection against peroxynitrite-induced apoptosis (or “stress”) against macrophages in an *in vitro* assay., but there appears to be no obvious correlation, nor a correlation of any kind, between protection of peroxynitrite-induced apoptosis of macrophages and the treatment of lupus or tail and/or mane eczema in mammals as recited in claims 1 and 3.

In view of the above-mentioned differences between treating lupus, tail and mane eczema as recited in claims 1 and 3 and treating stress as allegedly taught in the prior art, and the fact that neither Flynn, Widy-Tyszkiewicz, Singh, McClung or Sandoval discloses that the individual components can be used to treat lupus and/or tail and mane eczema, one skilled in the art would not have been motivated to combine Flynn, Widy-Tyszkiewicz, Singh, McClung and Sandoval to render claims 1 and 3 obvious.

Irrespective of the alleged correlation between stress and lupus and tail and/or mane eczema, not all of the individual components of Flynn, Widy-Tyszkiewicz, Singh, McClung and Sandoval are used for treatment of stress. In addition, there is a distinction between stress in the sense of mental stress

experienced by people and oxidative stress experienced on a cellular level by macrophages as mentioned by Sandoval. In contrast, *Piper methysticum* is disclosed for having remedial properties against anxiety disorders while leaves of *Melissa officinalis* are disclosed for treatment of insomnia. Therefore, Applicants respectfully submit that the oxidative protection provided by *Uncaria tomentosa* in Tomatosa cannot be “useful for the same purpose” as the anti-stress activity relating to mental stress conferred by other components in the other cited art documents, nor is it clear that *Melissa officinalis* used in Widy-Tyszkiewicz has any purpose in treating stress.

The Applicants, therefore, respectfully request that the rejection to Claims 1 and 3 under 35 U.S.C. § 103(a) be withdrawn. Claims 2-9, dependent on independent claims 1 and 3, are patentable for the reasons stated above with respect to claims 1 and 3 as well as for their own merits. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claims 1 and 3 and all claims dependent thereon.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants hereby petition for a one (1) month extension of time for filing a reply to the outstanding Office Action and submit the required \$130.00 extension fee herewith.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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By


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Attachment: Replacement Abstract (1 p.)